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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,383	02/05/2004	Daqing Che	P1054US00	3324

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EXAMINER	
HUGHES, ALICIA R	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
07/19/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,383	CHE ET AL.	
	Examiner	Art Unit	
	ALICIA R. HUGHES	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1 and 3-24 are pending and the subject of this Office Action.

Applicants' arguments, filed on 30 September 2009, have been fully considered and it is deemed to be persuasive regarding the previous rejection. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn.

Upon reconsideration of the pending claims, as presented, the following new rejections are applied. They constitute the complete set of rejections being applied to the instant application presently.

Claim Rejections – 35 U.S.C. §§ 101 and 112.2

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-21 and 24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to nonstatutory subject matter. "Use" claims are nonstatutory because they are claims that fail to fall within one of the 35 USC 101 statutory classes of invention because "use" claims are inclusive of reasonable interpretations of product, method of using, and method of making. Such combined inventions are not statutory under 35 USC 101. The Applicant claims use of

amorphous atorvastatin calcium prepared by a number of process for treating hypercholesterolemia and based on the foregoing, the same is rejected pursuant to 25 U.S.C. 101

Claims 20-21 and 24 are also rejected under 35 U.S.C. 112, second paragraph. Specifically, since the claimed invention is not supported by either an Applicant asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejection – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 3 and 8-24 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,087,511 [hereinafter referred to as "Lin et al"](the reference is being considered in its totality)[1].

The teachings of Lin et al as set forth in this Office's Actions of 08 February 2008, 02 December 2008 and 01 April 2009 are incorporated herein by reference in their entirety.

Applicants consistently argue that Lin et al teaches away from the instant invention, because the step reversal addition (adding the atorvastatin salt solution to the calcium chloride or calcium acetate solution), as well as Applicants' direct one step process versus the two step

[1] Lin et al is cited on Applicants' IDS.

process found in the '511 Patent is not obvious to a person of ordinary skill in the art. Applicant also notes a reduced combined time for filtration and washing, which is more than a 50% reduction, when Examples 2 and 3 are compared with Example 1. However, the scope of the pending claims as written exceeds the scope of the unexpectedly faster results in the specification. As a result, claim 1 is still properly rejected over Lin et al.

Additionally, as the Examiner has stated prior, the balance of Applicants' arguments are not persuasive, most notably, because of the open claim language comprising encompasses the scope of the full invention. And more particularly, as noted prior, Lin et al disclose a novel process for making amorphous atorvastatin hemi calcium salt, noting that the same is useful as an inhibitor of HMG-CoA and therefore, useful in the treatment of hypercholesterolemia (Col. 1, lines 13-21).

As part of the process, w*hen the organic layer is again discarded, the aqueous solution of the sodium salt is heated and to the solution added calcium acetate hemihydrate dissolved in water*. Shortly thereafter, the mixture is seeded with a slurry of crystalline atorvastatin. Some time thereafter, the mixture is heated, then cooled, filtered, and wished with a solution of water and methanol followed by water. The resulting atorvastatin solid is dried under a vacuum to give the crystalline form, and through a process disclosed in Example 2, the crystalline form because amorphous atorvastatin (Col. 5, lines 11-65).

As a result of the foregoing, one of ordinary skill in the art would have been motivated to perform the instant invention based on the disclosures in Lin et al because as noted therein, although amorphous atorvastatin solids were known to exist in advance of the advent of crystalline atorvastatin, "the production of amorphous atorvastatin by the previously disclosed

processes was not consistently reproducible (Col. 1, lines 61-65). Further, it was also known that the bioavailability patterns of drugs often differ based on whether their forms are amorphous or crystalline, for example, making it desirable to have a procedure for converting the crystalline form to the amorphous form (Col. 2, lines 1-7).

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to prepare amorphous atorvastatin calcium by the hydrolysis of atorvastatin lactone to form atorvastatin sodium salt, to suspend the same into a solution of aqueous calcium acetate, and then, to isolate and dry the same to form amorphous atorvastatin calcium salt and that the same would be effective in the treatment of hypercholesterolemia.

Claims 4-7 are rejected under 35 U.S.C. §103(a) as being obvious over Lin et al in view of U.S. Patent Pre-Grant Publication No. 20050267198 A1 [hereinafter referred to as "Tessler et al"].

Tessler et al teach that amorphous atorvastatin hemi-calcium may be prepared by treating any other form of atorvastatin hemi-calcium with acetone at room temperature to reflux temperature for between a few hours and 25 hours, preferably about 16 hours (Page 7, Para. 89). A preferred starting material is Form V and moreover, amorphous atorvastatin hemi-calcium also may be prepared by ball milling of any crystalline form of atorvastatin hemi-calcium (Page 7, Para. 91; Page 12, Claim 119).

One of ordinary skill in the art would be motivated to combine the teachings of Tessler et al with the teachings of Lin et al to arrive at the instant invention given the overlap in scope of the teachings in both references, most notably, the crystalline form of atorvastatin, how it is prepared and used in other forms of atorvastatin.

In view of the foregoing, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was contemplated to prepare amorphous atorvastatin

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614